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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,599	10/03/2000	Leigh T Canham	124-796	1219

23117 7590 11/05/2003

NIXON & VANDERHYE, PC  
1100 N GLEBE ROAD  
8TH FLOOR  
ARLINGTON, VA 22201-4714

EXAMINER
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BENNETT, RACHEL M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/05/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/647,599

Applicant(s)

CANHAM ET AL.

Examiner

Rachel M. Bennett

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 144-153 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 144-153 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

The examiner acknowledges receipt of Amendment D filed 8/15/03.

### *Specification*

#### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 144-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Canham et al. (WO 97/06101).

Applicants claim a method of therapeutic or prophylactic treatment comprising the steps of: (a) implanting a silicon implant into a human or animal, the implant comprising a drug and resorbable mesoporous silicon, the drug being at least partly located in the pores of the silicon; and (b) allowing the porous silicon to erode.

Canham et al. disclose resorbable porous silicon, specifically mesoporous silicon, implants that release active agents such as calcium, sodium or phosphorus. The silicon is

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impregnated with the calcium, sodium or phosphorus. The porosity of the implants is within the instant claimed ranges. Canham does not distinctly teach the implants are to erode for an interval between one month and two years.

It is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to tailor the resorption profile of the implants on the basis of the teachings of Canham that the rate of resorption of the implant is based upon the porosity of the silicon and the motivation of providing an active agent for a particular time.

***Response to Arguments***

4. Applicant's arguments filed 8/15/03 have been fully considered but they are not persuasive. Furthermore, the Declaration filed on 8/15/03 under 37 CFR 1.131 has been considered but is ineffective to overcome the WO 97/06101 reference.

Applicants argue WO '101 does not disclose a resorbable mesoporous silicon implant having a drug located in it pores. Applicants argue this is supported by Professor Canhman's declaration. The examiner refers to WO '101, wherein Chanham teaches the silicon is impregnated with the calcium, sodium or phosphorus. Therefore it is the position of the examiner, that "impregnated" with calcium by definition - to cause to be filled, imbued, permeated, or saturated or to permeate thoroughly - reads on the limitation of "a drug being partly located in the pores of the porous silicon". Applicants also argue, supported by paragraph 6 of Professor Canhma's declaration, that WO '101 would lead the skilled person away from use of resorbable mesoporous silicon for drug delivery. Applicants argue this is because the resorbable mesoporous silicon would corrode. The examiner points out that the Professor Canhma's declaration states the "resorbable materials would erode when implanted". Therefore,

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is the position of the examiner the eroding of the resorbable mesoporous silicon is desired when developing a controlled drug release implant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the silicon because it erodes when implanted in order to obtain a controlled drug release.

### ***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (703) 308-8779. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

rmb

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600